

# SUMMARY OF PROPOSED CHANGES TO MAINE MILK RULE

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NOTE: Underlined text is added language; ~~strikeout~~ text is to be deleted

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v.	Table of Contents	SECTION XIII DRUG RESIDUE
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		C. 3.APPEAL PROCESS .....7376
1-38	Section I. A.	Renumber definitions from Automatic Milking Installation to Yogurt
6	Section I.A.	7.ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS- “Aseptically processed milk and milk products” are products <u>that have been subjected to sufficient heat processing and packaged in a hermetically sealed in a container, to conform to the applicable requirements of and so thermally processed in conformance with Title 21 CFR 113 and the provisions of this rule so as and to maintain under the the commercial sterility of the product free of microorganisms capable of reproducing in the product under normal non-refrigerated conditions, of storage and distribution. The product shall be free of viable microorganisms (including spores) of public health significance.</u>
6	Section I.A.	8. <u>AUTOMATIC MILKING INSTALLATION (AMI) – The term automatic milking installation covers the entire installation of one or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking, cooling, cleaning and sanitation.</u>
6.	Section I.A.	1314. COMMISSIONER – “Commissioner” means the Commissioner of the

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
7	Section I.A.	<u>16. COOLING POND</u> – A cooling pond is a man-made structure designed for the specific purpose of cooling cows.
9	Section I. A.	<del>1820.DAIRY</del> <u>DAIRY</u> OR DAIRY FARM – “Dairy or dairy farm” means any place or premises where one or more cows, goats, <del>or</del> sheep, <del>water buffalo, or other</del> <u>hooved mammal</u> are kept, and from which a part or all of the milk or milk product(s) are sold or offered for sale.
10	Section I. A.	<del>2224.</del> <u>24.</u> DRY CURD COTTAGE CHEESE – (b)(1)(b) <i>note: change is in last line</i> pressed, chilled, worked, <u>and</u> seasoned with salt.  (b)(i)(c) <i>note: change is in 5th line</i> to reach a final pH value is <u>in</u> the range of 4.5-4.8, and it is held until it becomes
13	Section I. A.	<del>27. FROZEN DAIRY DESSERT</del> – “Frozen Dairy Dessert” means ice cream and frozen custard, goat milk ice cream, sherbet and frozen yogurt.  <del>28. FROZEN DAIRY DESSERT MIX</del> – “Frozen dairy dessert mix” means any unfrozen mixture to be used in the manufacture of frozen dairy dessert for sale or resale and shall contain in whole or in part the ingredients enumerated under the definition of frozen dairy dessert.
13	Section I. A.	30. FROZEN YOGURT (a) 13 <sup>th</sup> line ...frozen yogurt is less than 0.3 percent, the manufacturer may establish compliance with this section by disclosing to the <del>regulatory authority</del> <u>Department</u> its quality control records that demonstrate as a result of...
16	Section I. A.	<u>40. HOOVED MAMMALS MILK</u> – <u>Hooved mammals milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one (1) or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Rule.</u>

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16	Section I. A.	<p><del>4041.</del> ICE CREAM AND FROZEN CUSTARD -</p> <p>(a)</p> <p>(i) “Ice cream” is a food produced by freezing, while stirring, a mix.....  .....characterized by the addition of flavoring ingredients. <u>If eggs or egg yolk solids are used as an ingredient, they must be pasteurized or, if not pasteurized, the mix must be pasteurized after the eggs or egg yolk solids are added.</u></p>
21	Section I. A.	<p><u>43. INDUSTRY PLANT SAMPLER – A person responsible for the collection of official samples for regulatory purposes at a milk plant, receiving station or transfer station as outlined in Section XIII. of this Rule. This person is an employee of the milk plant, receiving station or transfer station and is evaluated at least once every two (2) year period by a State Sampling Surveillance Officer or a properly delegated Sampling Surveillance Regulatory Official.</u></p>
24	Section I.A.	<p><del>4951.</del> MILK –</p> <p>“Milk” is the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats, <del>or</del> sheep, <u>water buffalo or other hooved mammal.</u> Milk from cows that is in final....</p>
25	Section I. A.	<p><del>5254.</del> MILK PRODUCER – “Milk producer” means any person who operates a dairy farm and <u>provides,</u> sells or offers milk or milk product(s) for sale.</p>
25	Section I, A.	<p><del>5355.</del> MILK PRODUCTS</p> <p><u>Powdered dairy blends may be labeled Grade “A” and used as ingredients in Grade “A” dairy products, such as cottage cheese dressing mixes or starter cultures used to produce various Grade “A” cultured products, if they meet the requirements of this Rule. If used as an ingredient in Grade “A” products, such as those listed above, blends of dairy powders must be blended under conditions, which meet all applicable Grade “A” requirements. Grade “A” powder blend must be made from Grade “A” powdered dairy products, except that small amounts of functional ingredients, (total of all such ingredients shall not exceed 5% by weight of the finished blend) which are not Grade “A” are allowed in Grade “A” blends when the finished ingredient is not available in Grade “A” form, i.e. sodium caseinate. This is similar to the existing FDA position that such</u></p>

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28	Section I. A.	<p><del>59</del>61. MISBRANDED MILK AND MILK PRODUCTS</p> <p>n.(i) If it contains saccharin, its label and labeling bear the following statement: ‘USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS’. Such statement shall be located in a conspicuous place on such label and labeling as proximate as possible to the name of such food and shall appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.</p> <p>(<del>+</del>) (<del>ii</del>) If it contains saccharin and is offered for sale, but not for immediate consumption, at a retail establishment, unless such retail establishment displays prominently, where such food is held for sale, notice (provided by the manufacturer of such food pursuant to subparagraph (ii)) for consumers respecting the information required by paragraph (n) to be on food labels and labeling.</p> <p>(<del>ii</del>) (<del>iii</del>) Each manufacturer of food which contains saccharin and which is offered for sale by retail establishments but not for immediate consumption shall take such action as may be necessary to provide such retail establishments with the notice required by subparagraph (i).</p>
29	Section I. A.	<p><del>64</del>63. NOT PASTEURIZED - “Not pasteurized” means any milk or milk product that has not been subjected to the temperature and time requirements of pasteurization using equipment designed for pasteurization or has not been aseptically processed and packaged. This does not apply to <del>farm cheese or to</del> cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.</p>
37	Section I. A.	<p><u>82. WATER BUFFALO – Water buffalo milk is the normal lacteal secretion, practically free of colostrums, obtained by the complete milking of one</u> <u>(1) or more healthy water buffalo. Water buf</u> <u>(2) falo milk shall be produced</u> <u>according to the sanitary standards of this Rule. The word “milk” shall be</u> <u>interpreted to include water buffalo milk.</u></p>

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
39,40	Section III.	<p>LICENSING AND PERMITS</p> <p>C. Permits</p> <p>1. <del>Milk Producer—Every milk producer shall hold a permit issued by the Commissioner. There is no fee for a permit.</del></p> <p><del>Only a person who complies with the requirements of this rule shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations.</del></p> <p><del>A milk producer who holds a permit shall operate his/her dairy farm or portable/temporary milking parlor in substantial compliance with the provisions of this rule.</del></p> <p>2. <del>Milk Sampling, Hauling and Transportation</del></p> <p>(a) <del>All bulk milk hauler/samplers based in Maine must obtain a permit from the Department.</del></p> <p>(b) <del>Dairy plant samplers are not required to hold a permit from the Department but are evaluated every two years by the State Sampling Surveillance Officer.</del></p> <p>(c) <del>Milk tank truck drivers are not required to hold a permit from the State.</del></p> <p>(d) <del>Receiving stations, milk tank truck cleaning facilities, and transfer stations must obtain a permit from the Department.</del></p> <p>(e) <del>Milk transportation companies based in Maine must obtain a permit from the Department.</del></p> <p><u>Every milk producer, bulk milk hauler and sampler, milk transportation company, receiving station, transfer station and portable/temporary milking parlor shall hold a valid permit in accordance with the requirements of this rule and state law. A permit may be suspended for any failure to comply with these requirements. Permits are issued at no cost and are not transferable between person, businesses or farms.</u></p>

Permits are issued to:

1. Milk Producer: A permit authorizes the milk producer to ship, sell and/or receive milk

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
39,40	Section III (cont)	<p><u>2. Bulk Milk Hauler/Sampler: A permit authorizes the bulk milk hauler/sampler to collect official samples and/or transport raw milk from a farm and/or raw milk products to or from a farm, milk plant, receiving station or transfer station.</u></p> <p><u>3. Receiving stations: A permit authorizes the receiving station to receive, collect, handle, store or cool and prepare raw milk for further transporting.</u></p> <p><u>4. Milk Tank Truck Cleaning Facilities: A permit authorizes the milk tank truck cleaning facility to clean and sanitize a milk tank truck.</u></p> <p><u>5. Transfer Stations: A permit authorizes a transfer station to transfer milk or milk products directly from one milk tank truck to another.</u></p> <p><u>6. Milk Transportation Company: A permit authorizes the milk transportation company to transport raw milk in a milk transport tank driven by a milk tank truck driver. Milk tank truck drivers are not required to obtain individual permits.</u></p> <p><u>7. Portable/temporary milking parlor: A permit authorizes the operator of a portable/temporary milking parlor to ship, sell or receive milk.</u></p>
40	Section IV.	<p>INSEPTION</p> <p>5<sup>th</sup> line:</p> <p>...standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and <del>his/her</del> <u>their</u> bulk milk pickup tank and its appurtenances shall be inspected by the Department.</p>
40	Section IV. B.	<p>Inspect each <del>dairy</del> <u>dairy industry</u> plant sampler, bulk milk hauler/samplers' pickup and sampling procedures at least once every 24 months;</p>

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41	Section IV. H.	<u>Should the violation of any requirement set forth in this Section, or in the case of a milk hauler/sampler or industry plant sampler also Section VI, be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before 3 days. This second inspection shall be used to determine compliance with requirements of Section IV or in the case of a milk hauler/sampler or industry plant sampler also Section VI. Any violation of the same requirement of Section IV, or in the case of a milk hauler/sampler or industry plant sampler also Section VI on such second inspection, shall in the case of a milk hauler/sampler call for permit suspension in accordance with 7 M.R.S.A § 2902-A or in the case of an industry plant sampler, shall require that the collection of official regulatory samples be ceased until the industry plant sampler has been successfully re-trained and re-evaluated by the Department.</u>						
44	Section V. Table 1.	<table><tr><td>Phosphatase***.....</td><td><del>Less than 1 microgram per ml by the Scherer-Rapid Method. Less than 350 milliunits/L for fluid products and less than 500 for other milk products by the Flourometer or Charm ALP or equivalent.</del></td></tr></table>	Phosphatase***.....	<del>Less than 1 microgram per ml by the Scherer-Rapid Method. Less than 350 milliunits/L for fluid products and less than 500 for other milk products by the Flourometer or Charm ALP or equivalent.</del>				
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44,45	Section V. Table1.	<table><tr><td>Drugs .....</td><td>No positive results on drug residue detection methods as referenced in Section XII – <del>The examination of Milk and milk products</del> <u>Methods of Analysis.</u></td></tr><tr><td>Drugs** .....</td><td>No positive results on drug residue detection methods as referenced in Section XII-<del>The examination of milk and milk products</del> <u>Methods of Analysis</u>, which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.</td></tr><tr><td>Drugs** .....</td><td>No positive results on drug residue detection methods as referenced in Section XII-<del>The examination of milk and milk products</del> <u>Methods of Analysis</u>, which have been found to be acceptable for use with aseptically processed milk and milk products.</td></tr></table>	Drugs .....	No positive results on drug residue detection methods as referenced in Section XII – <del>The examination of Milk and milk products</del> <u>Methods of Analysis.</u>	Drugs** .....	No positive results on drug residue detection methods as referenced in Section XII- <del>The examination of milk and milk products</del> <u>Methods of Analysis</u> , which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.	Drugs** .....	No positive results on drug residue detection methods as referenced in Section XII- <del>The examination of milk and milk products</del> <u>Methods of Analysis</u> , which have been found to be acceptable for use with aseptically processed milk and milk products.
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		<p>Drugs**</p> <p>No positive results on drug residue detection  Methods as referenced in Section XII-<del>The examination of milk and milk products</del> <u>Methods of Analysis</u> which have been found to be acceptable for use with not pasteurized milk and milk products.</p>
45	Section V. Table 1.	**Not Applicable to <u>acidified or cultured</u> products.
45	Section V. Table 1	<p>SINGLE SERVICE CONTAINER Bacterial limits      The residual bacteria count shall not exceed 50 per container, <u>except that in containers less than 100 mL, the count shall not exceed ten (10) colonies.</u></p> <p>MANUFACTURERS</p>
46	Section VI. A.1.	<p>ABNORMAL MILK - <del>Cows</del> <u>Lactating animals</u> which show evidence of the secretion of <del>abnormal</del> milk <u>with abnormalities</u> in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. <del>Cows Lactating animals producing abnormal milk, that is lactating animals which have been treated with, or cows which</del> have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgment of the Department, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the Department may direct. <u>For applicability to Automatic Milking Installations refer to Appendix Q, 2003 Pasteurized Milk Ordinance.</u></p>
47	Section VI. A. 4.	<p>COWYARD – The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes, Provided, that in loafing or lactating animal-housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating animal's udder and flanks. <u>Cooling ponds shall be allowed provided they are constructed and maintained in manner that does not result in the visible soiling of flanks, udders, bellies and tails of lactating animals exiting the pond.</u> Waste feed shall not be allowed to</p>
49	Section VI. A. 13.	<p>milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking. <u>Provided that the sanitizing of teats shall not be required if the udder is dry and the teats have been thoroughly cleaned (not dry wiped) and dried (manually wiped dry) prior to milking</u> Wet hand milking is prohibited.</p>

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50	Section VI. A. 15.	<p>DRUG AND CHEMICAL CONTROL - Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by cleaners and sanitizers, drugs and drug administering equipment.</p> <p>a. <u>Lactating animals treated with medicinal agents must be:</u></p> <ol style="list-style-type: none"> <li>1. <u>Identified, i.e. leg bands, chalk marks, etc.; and/or</u></li> <li>2. <u>Segregated; or</u></li> <li>3. <u>Otherwise handled in a manner such as to preclude the adulteration of milk offered for sale.</u></li> </ol> <p>b. <u>Treatment Records (which may consist of paper and file folders, card files, appointment book type calendars, monthly calendars, chalk boards (temporary records), electronic computer records, etc) must include the following information:</u></p> <ol style="list-style-type: none"> <li>1. <u>Identity of the animal (s) treated;</u></li> <li>2. <u>Date(s) of treatment;</u></li> <li>3. <u>Drug(s) or other chemicals administered;</u></li> <li>4. <u>Dosage administered;</u></li> <li>5. <u>Milk discard time; and</u></li> <li>6. <u>Withdrawal time prior to slaughter, even if zero.</u></li> </ol> <p>c. <u>Maintenance of Records: The proper use or misuse of some animal drugs may cause prolonged residues in milk (4 to 45 days) and meat (18 to 24 months). Verification of drug treatment records may be necessary in the event of an investigation or trace back by the industry or Department to identify specific treated animal(s) that may be related to a milk or dairy beef residue. Producers should maintain all treatment records for a minimum of two (2) years in the event of a need to trace back or follow up on a confirmed milk or meat residue.</u></p> <p>d. <u>Treated animal must be quarantined or segregated, or otherwise handled in a manner to preclude the sale of milk or the offering of treated animals for sale for slaughter prior to the end of the prescribed withdrawal time</u></p> <p>e. <u>Education of all farm personnel involved in treating animals on proper drug use and methods to avoid marketing adulterated milk or meat for human food</u></p>
51	Section VI. A.18.	<p>COOLING - Raw milk for pasteurization shall be cooled to 7°C(45°F) or less within 2 hours after milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F). <u>All farm bulk</u></p>

milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature-recording device.

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51	Section VI. A.	<u>20. Requirements for Automatic Milking Installations can be found in Appendix Q, 2003 Pasteurized Milk Ordinance.</u>
54	Section VI. B.	<u>23. Requirements for HACCP systems in Dairy Plants can be found in Appendix K, 2003 Pasteurized Milk Ordinance.</u>
62	Section VII	ANIMAL HEALTH
		<u>A. Tuberculosis Testing Requirements</u>

All milk shall be from herds in areas ~~which~~ that are located in a Modified Accredited Advanced Tuberculosis status or greater as determined by the U.S. Department of Agriculture. Provided, that in an area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free or shall have passed an annual tuberculosis test, or the area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the area and that it is approved by the Food and Drug Administration, the U.S. Department of Agriculture, and the Department. And also provided, that milk from cow, goat, sheep, water buffalo or other hooved mammal herds used for not pasteurized product production shall be from herds which have been tested every 3 years for tuberculosis with an allowable maximum grace period not exceeding 2 months.

#### B. Brucellosis Testing Requirements

1. All cow milk shall be from herds under a brucellosis eradication program ~~which~~ that meets one of the following conditions:

~~A.~~ (a) Located in a Certified Brucellosis-Free Area as defined by the U.S. Department of Agriculture and enrolled in the testing

program for such areas; or

- ~~B.~~ (b) Meet U.S. Department of Agriculture requirements for an individually certified brucellosis-free herd; or

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62,63	Section VII (cont)	<p><del>C.</del> (c) Participate in a milk ring testing program at least two times per year at approximately 180 day intervals and all herds with positive milk ring test results shall have the entire herd blood tested within 30 days from the date of the laboratory ring test; or</p> <p><del>D.</del> (d) <u>Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding 2 months.</u></p>

~~For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.~~

2. Goat, milk and sheep, water buffalo, or any other hooved mammal except cow milk for milk product production pasteurization, or ultra-pasteurization or aseptic processing shall be from a herd or flock, which that meets one of the following conditions:

- (a) ~~which~~ Has passed an annual whole herd or flock tuberculosis and brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or
- (b) ~~From a herd or flock which~~ Has passed an initial whole herd brucellosis test, followed ~~only~~ by testing any outside, new acquisition replacement animals ~~or any animals entering the milking group or sold as dairy animals;~~ or by
- (c) ~~Has passed~~ a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test; or
- (d) ~~Has passed an annual random blood-testing program~~ sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found.

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63,64	Section VII (cont)	<u>The following table will provide the random sampling size needed to achieve 99% confidence with a P value of 0.05.</u>

<b>Herd/Flock Size</b>	<b>Sampling Size</b>	<b>Herd/Flock Size</b>	<b>Sampling Size</b>
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86
250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	81	100000	90

~~Milk from goat herds used for raw milk product production shall be from herds which have been tested every 3 years for tuberculosis with an allowable maximum grace period not exceeding 2 months.~~

### C. Other Testing Requirements

For diseases other than brucellosis and tuberculosis, the Department shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

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65	Section XI. A.	A. Milk plant operators who have received reports, under this section, from employees who have handled pasteurized milk, pasteurized milk products or associated product contact surfaces shall immediately report these facts to the <del>appropriate milk Regulatory Agency</del> <u>Department</u> .
68	Section XII. A. 6.	During any consecutive 6 months at least 4 samples <u>sets</u> of single service containers <u>from each manufacturing line</u> , shall be collected by the Department, in at least 4 separate months, except when 3 months show a month containing 2 sampling dates separated by at least 20 days from every manufacturer. <u>A sample set is at least four (4) containers.</u>
68	Section XII. A. 10.	Water samples, from the water supply for the milk house and milking operations, shall be taken every 3 years. Water supplies with buried well casing seals, shall be sampled at intervals no greater than 6 months apart. Water samples, from the water supply for milk plant purposes, shall be sampled every 6 months <u>for Interstate Milk Shippers plants and every 12 months for all other plants. Recirculating water shall be sampled every 6 months for all dairy plants. Dairy farms and dairy plants who use municipal water supplies shall be exempt from these water testing requirements.</u>
69	Section XII B.3.	Required bacterial counts, <u>coliform determinations</u> , somatic cell counts and cooling temperature checks shall be performed on heat treated milk products.
69	Section XII. B.	7. <u>When multiple samples of the same milk or milk products, except for aseptically processed milk and milk products, are collected from the same producer or processor from multiple tanks or silos on the same day, the laboratory results are averaged arithmetically by the Department and recorded as the official results for that day. This is applicable for bacterial (standard plate count and coliform), somatic cell count and temperature determinations only.</u>

69	Section XII. B.	8. <u>Milk from animals not currently in this Rule may be labeled as Grade “A” and IMS listed upon FDA’s acceptance of validated drug residue test methods for compliance with this Section and Section XIII.</u>
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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
70	Section XII. C. 2.	<p>...telephone and/or pager) and they will conduct a plant inspection as soon as possible. This inspection shall note the <del>probably</del> <u>probable</u> cause of the violation(s) and any corrective action(s) necessary. After inspection, the plant...</p> <p>... Product will be sampled on an accelerated schedule (<u>not more than 2 samples per week for 3 weeks</u>).</p>
70	Section XII. C. 3.	<p>When a producer’s bulk tank milk is in violation of standard for 3 of the last 5 samples, the permit shall be suspended by the department and the following steps shall be taken: <del>(a) department shall suspend the producer’s permit, and issue a temporary permit, (b) (a) For violation of bacterial or cooling temperature standard, the Department shall conduct a farm inspection. This inspection shall note the probable cause of the violation(s) and any corrective action(s) necessary. . The producer’s permit shall be restored upon inspection. A permit shall be issued upon inspection. (b) For violation of somatic cell standard, permit will be issued when an official bulk tank sample is tested within the standard established by this Rule at an official laboratory.</del></p> <p><u>For bacterial or somatic cell violations, the producer’s bulk tank milk will be sampled on an accelerated schedule (not more than 2 samples per week for 3 weeks). Once the accelerated sampling has begun, the previous test history will not be used to calculate 2 out of 4 or 3 out of 5 violations. Calculations will be based on test results from the accelerated sampling schedule.</u></p>
71	Section XII.	<p><u>D. INDEPENDENT TESTING OF NOT PASTEURIZED MILK PRODUCTS</u></p> <p><u>When the official milk laboratory operated by the department has tested not pasteurized milk products and determined that those milk products do not meet the standards for not pasteurized milk products established by this rule, the person operating the milk plant that processed the milk products may request further testing by an independent FDA certified laboratory. The not pasteurized</u></p>

milk products must not be sold pending the completion of the independent testing.

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
71	Section XII.D.(cont)	<p><u>Within three (3) business days of receipt by the department of a request for independent testing, the State Dairy Inspector shall obtain duplicate samples of the not pasteurized milk products from the processor. These samples will be delivered by the State Dairy Inspector to the state milk laboratory and shipped by the Department to an independent FDA certified laboratory for testing. The processor shall be responsible for the cost of shipping and testing performed by the independent FDA certified laboratory. The test results will be sent by the Department to the processor within 24-hours of receiving the results.</u></p> <p><u>The not pasteurized products in dispute may be offered for sale only after testing at the official milk laboratory and the independent official laboratory has been completed and the department has received results from either laboratory which are within the established standards set forth in this rule. If the results from both the independent official laboratory and the official milk laboratory do not meet the standards for not pasteurized products, the products must not be sold until they meet the established standards.</u></p>
71	Section XII. E.. 1.	<p>Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examination shall be in substantial compliance with the <del>17</del> 16<sup>th</sup> Edition of Standard Methods for the Examination of Dairy Products of the American Public Health Association</p>
72	Section XIII. A. 1.	<p>MONITORING AND SURVEILANCE - Milk plants shall screen all bulk milk pickup tankers, <u>regardless of final use</u>, for beta lactam drug residues. <u>Specific requirements for establishing a drug residue testing program can be found in Appendix N of the 2003 Pasteurized Milk Ordinance</u> Additionally, other drug residues shall be.....</p> <p>...Samples collected under this random sampling program shall be analyzed as specified by <u>FDA</u>. (Refer to M-a-75)</p>

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
72	Section XIII. A. 1.	<u>The bulk milk pickup tanker shall be sampled after the last producer has been picked up and before any additional commingling. The sample must be representative. Bulk milk pickup tanker testing shall be completed prior to processing the milk. Industry samplers shall be evaluated according to the requirements specified in Section XII, THE EXAMINATION OF MILK AND AND MILK PRODUCTS of the rule.</u> Bulk milk pickup tanker samples found to be confirmed positive for drug residues shall be retained as determined necessary by the Department. <del>Milk plants shall also record all sample results and retain such records for a period of six months.</del>
73	Section XIII. A. 2.	<i>delete</i> ". “ at end of the word “TRACEBACK” REPORTING AND FARM TRACEBACK: – When a bulk milk pickup tanker is...
73	Section XIII. A.	<p><u>3. RECORD REQUIREMENTS</u>  <u>Results of all testing may be recorded in any format acceptable to the Department and shall include at least the following information:</u>  <u>1. Identity of the person doing the test;</u>  <u>2. Identity of the bulk milk pickup tanker being tested (include the BTU number(s) of the farms present on the tanker);</u>  <u>3. Date/time the test was performed (Time, Day, Month and Year);</u>  <u>4. Identity of the test performed/lot #/any and all controls (+/-);</u>  <u>5. Results of the test;</u>  <u>6. Follow-up testing if initial test was positive/any and all controls (+/-);</u>  <u>7. Site where test was performed and</u>  <u>8. Prior test documentation shall be provided for a presumptive positive load.</u></p> <p><u>Records of all sample results shall be maintained for a minimum of six (6) months by the milk plant at the location where the tests were run, and/or another location as directed by the Department.</u></p>
73	Section XIII. B. 1.	MONITORING AND SURVEILLANCE – The Department shall monitor milk plant surveillance activities <u>during either</u> <del>by making</del> <u>routine or</u> unannounced,

on-site quarterly inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. Samples should be collected and analyzed from at least 10% of the bulk milk pickup tankers scheduled to arrive on the day of the inspection. The method used shall be appropriate for the drug being analyzed and shall be capable of detecting the same drugs at the same concentrations as the method being used by industry.

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
74	Section XIII. B. 1.	(b) Is each producer's milk represented in a testing program for drug..
74	Section XIII. B.1.	<p><u>To satisfy these requirements:</u></p> <p><u>1. There should be an agreement between the Department and industry that would specify how this notification is to take place. This notification must be "timely" for example by telephone or fax, and supported in writing</u></p> <p><u>2. The ultimate disposition should either be prearranged in an agreement between the Department and the industry, or physically supervised by the Department. The milk should be disposed of in accordance with the provisions of M-I-90-9 or an FDA and Department reviewed and accepted Beta lactam milk diversion protocol for use as animal feed</u></p> <p><u>3. All screening test positive (confirmed) loads must be broken down (producer traceback) using the same or an equivalent test method (M-I-96-10, latest version). Confirmation tests (load and producer trace back/permit action) shall be performed by an Official or Officially Designated Laboratory or Certified Industry Supervisor. Positive producers shall be handled in accordance with Section XIII of this rule</u></p> <p><u>4. The suspension and discontinuance of farm bulk milk tank pick up is the responsibility of the industry, under the direction and supervision of the Department. At the discretion of the Department, records shall be maintained by industry and/or the Department that:</u></p> <p style="padding-left: 40px;"><u>a. Establish the identity of the producer and the identity of the load that tested positive; and</u></p> <p style="padding-left: 40px;"><u>b. Establish that no milk is picked up from the positive testing producer until the Department has fulfilled their obligations under Section XIII. B.2. of this rule and cleared the milk.</u></p> <p><u>Sufficient records shall be reviewed to assure that all farm bulk milk pickup tankers are sampled before commingling and the results were made available to the appropriate BTU (s).</u></p>
75	Section XIII.B.2	<p>(a) On farm changes in procedures necessary to prevent future occurrences as recommended by the <del>state regulatory agency</del> <u>Department</u>.</p> <p>(b) Discussion and education on the Drug Residue Avoidance Control measures outlined in the Milk and Dairy Beef Residue Prevention Protocol.</p>

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
75	Section XIII.B.2	<p><del>Second offense: Discussion and education on the Drug Residue—Avoidance Control measures outlined in the Milk and Dairy Beef Residue Prevention Protocol.</del></p> <p><del>Third offense within one year: Hearing scheduled and procedures initiated by Department for revocation of Permit.</del></p> <p><u>Permit Revocation: After a third violation in a twelve (12) month period, the Department shall initiate proceedings to revoke the producer’s Grade A permit.</u></p>
75	Section XIII.B. New 3.	<p><u>3. DEPARTMENT RECORDS</u></p> <p><u>In the event the industry reports a positive tanker result, the Department’s records should indicate the following:</u></p> <p><u>a. What were the Department’s directions?</u></p> <p><u>b. When was the Department notified? By whom?</u></p> <p><u>c. What was the identity of the load?</u></p> <p><u>d. What screening and/or confirmatory test(s) were used and who were the analyst(s)?</u></p> <p><u>e. What was the disposition of the adulterated milk?</u></p> <p><u>f. Which producer(s) was responsible?</u></p> <p><u>g. Record of negative test results prior to subsequent milk pickup from the violative producers(s).</u></p>
76	Section XIII.	<p>C.     3.     APPEALS PROCESS.</p>
77	Section XIV A.8.	<p>The <u>common name of the hooved mammal producing the milk</u> word “Goat” or “<del>Sheep</del>” shall precede the name of the milk or milk product when the product is or is made from <u>goat or sheep other than cattle’s milk respectively</u>. <u>As an example, “Goat”, “Sheep”, “Water Buffalo” or “Other Hooved Mammal” milk or milk products respectively.</u></p>
77	Section XIV. A. 10.	<p>The words “not pasteurized” if the milk or milk product has not been pasteurized. <del>All farm cheese products shall be labeled in accordance with 7 M.R.S.A. § 2109.</del> This does not apply to cheese that has been aged at a temperature above 35°F for at least 60 days prior to sale.</p>

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<u>Page #</u>	<u>Section</u>	<u>Changes</u>
78	Section XIV. A.18.	The use of the term “organic”, or “ <del>organically grown</del> ”, or “ <del>biologically grown</del> ” shall comply with <del>7 M.R.S.A. Chapter 103, Marketing Natural Organic Foods</del> <u>The Organic Foods Production Act of 1990 and 7 CFR Part 205, National Organic Program</u> ( <a href="http://www.ams.usda.gov/nop/NOP/standard.html">www.ams.usda.gov/nop/NOP/standard.html</a> )(2005).
78 - 80	Section XV	REFERENCES
		<ol style="list-style-type: none"> <li>1. Grade “A” Pasteurized Milk Ordinance and Appendices, <del>2001</del> <u>2003</u> Edition.</li> <li>7. Standard Methods for the Examination of Dairy Products, <del>16-17<sup>th</sup></del> Edition, 1992, American Public Health Association, 1015 Fifteenth Street, Washington, D.C., 20005.</li> <li>11. Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, <del>1999</del> <u>2005</u> Revision.</li> <li>12. Evaluation of Milk Laboratories, <del>1995</del> <u>2003</u> Edition, Food and Drug Administration, CFSAN, Office of Field Programs, Division of HACCP, Laboratory Quality Assurance Branch, HFH-450, 6502 South Archer Road, Summit-Argo, IL 60501.</li> <li>14. M-a-85, Beta-Lactam Test Methods for Use Under Appendix N of the PMO, Revision #7, <del>May 21, 1999</del> <u>#11 3-10-2004</u></li> <li>17. Methods of Making Sanitation Ratings of Milk Shippers, <del>1999</del> <u>2003</u> Edition, Public Health Service, Food and Drug Administration.</li> </ol>